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1. Summary of changes to the protocol
2. Original protocol
SUMMARY OF CHANGES TO PROTOCOL

We made the following changes to the original protocol:

1. Removal of the sponsor network on 12/21/15 before any participants started the study. We removed this component of the study because the technology to implement the sponsor network on Way to Health will not be ready and tested in time for the start of our study. In addition, our study has been delayed due to technical issues and some recruiting issues. We need to start our study as soon as possible to stay within our funding timeline. The sponsor network was a secondary component to the intervention. Our primary intervention is the use of daily financial incentives.

2. Addition of a research-only HbA1c on 2/29/16 for a small subset of participants because clinical and logistic scheduling issues prevented them from being able to get their HbA1c’s within the time window needed for the study. The research-only, point-of-care HbA1c were done at each participant’s usual diabetes clinic (e.g., Wood, King of Prussia, Bucks). The point-of-care HbA1c test involves a finger-prick, which is a usual part of the daily routine of a patient with type I diabetes. It was important that each participant have their 3-month HbA1c checked on the same machine as their baseline HbA1c to allow for accurate comparisons of the values. Participants were not billed for this research-only HbA1c since the study team covered the expense. The result of the research-only HbA1c test was not used for any clinical decision-making. A consent addendum was given to any participant requiring a research-only HbA1c.

3. Change to hypoglycemia monitoring protocol. Rather than contact participants for every severe hypoglycemia episode, we contacted each participant no more than once every 2 weeks for any glucose reading <50mg/dL since repeated calls may give the message that low glucose readings are “bad” when they are actually expected. On that call, we asked participants to contact us if they have any serious hypoglycemic events requiring the assistance of another person.
Title: BE In CONTROL - Behavioral Economic Incentives to Improve Glycemic Control among Adolescents and Young Adults with Type I Diabetes: A Randomized Controlled Trial

Short Title BE In CONTROL

Original Protocol Date: 8/18/15

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ABSTRACT

Context: (Background)
Glycemic control often deteriorates as patients with type 1 diabetes mellitus (DM1) reach adolescence and young adulthood and encounter with adhering to a daily medical regimen. Their non-adherence occurs in the context of decreasing parental involvement, developing maturity and transitioning from pediatric to adult care. Interventions using behavioral economic concepts and wireless devices that have been shown to increase adult adherence have not been fully incorporated into youth adherence research.

Objectives: (primary and important secondary objectives)
The objective of this study is to compare a novel approach using daily financial incentives and a tiered sponsor network to motivate adolescents and young adults with DM1 to improve glycemic control and adherence to daily glucose monitoring goals.

Study Design:
6-month randomized controlled trial with a 3-month intervention period and a 3-month follow-up period

Setting/Participants:
This study will be conducted at The Children’s Hospital of Philadelphia (CHOP) and the University of Pennsylvania. Participants will include approximately 90 adolescents and young adults who are 14-20 years old, diagnosed with DM1, and in suboptimal glycemic control (HbA1c >8.0 within 30 days of enrollment) and receive care from The CHOP Diabetes Center for Children.

Study Interventions and Measures:
Participants will be given daily glucose monitoring goals of ≥4 glucose checks per day with ≥1 readings within goal range (70-180 mg/dL) and provided with iHealth wireless glucometers. Half of the study participants will be randomized to the 3-month intervention arm on Way to Health. The intervention includes daily financial incentives ($60 in an account at beginning of each month with $2 daily loss if non-adherent) and a 2-level tiered sponsor network (youth select 2 people who will be notified of non-adherence after 2 and 5 consecutive days). The primary outcome will be HbA1c at 3 months compared to baseline. Secondary outcomes will include HbA1c at 6 months and the proportion of participants adherent to daily glucose monitoring goals. Exit interviews will elicit intervention feasibility and feedback from a youth perspective.
BACKGROUND INFORMATION AND RATIONALE

1.1 Introduction

The importance of improved glycemic control in reducing the risk of acute and long-term complications in type 1 diabetes mellitus (DM1) is well-recognized. However, glycemic control often deteriorates during adolescence and the transition to young adulthood, putting these individuals at high risk of adverse outcomes. Poorer glycemic control is attributed to difficulties adhering to the prescribed medical regimen, which includes daily blood glucose monitoring, insulin administration, and dietary guidelines. These challenges occur in the context of decreasing parental involvement and developing psychosocial maturity. Identifying effective interventions to engage adolescents and young adults in proper health management is important as these patients prepare to transition to adult models of care, which require independent self-management and self-advocacy skills.

1.2 Relevant Literature and Data

Though the benefits of improved adherence have been demonstrated, interventions to increase adherence among youth have often shown only relatively small gains. A meta-analysis of adherence promotion interventions for pediatric DM1 found that interventions that targeted both direct, behavioral processes (e.g., frequency of blood glucose monitoring) and emotional, social or family processes were more effective or potent. Behavioral economic concepts, such as loss aversion, anticipated regret, and overweighting of small probabilities, have been effective for increasing adherence to chronic disease management regimens in adult populations but have not been fully incorporated into youth adherence research. Wireless devices offer a promising approach to improve care through self-monitoring with minimal additional effort, especially when combined with efforts to enhance patient engagement, such as financial incentives and peer support. Home-based monitoring that augments and allows for less reliance on medical visits is particularly attractive for adolescents and young adults who tend to access outpatient care less frequently.

1.3 Compliance Statement

This study will be conducted in full accordance of all applicable Children’s Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented. The investigators will perform the study in accordance with this protocol, will obtain consent and assent, and will report unanticipated problems involving risks to subjects or others in accordance with The Children’s Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

2 STUDY OBJECTIVES

The objective of this study is to compare a novel approach using daily financial incentives and a tiered sponsor network to motivate adolescents and young adults with type 1 diabetes to improve glycemic control and adherence to daily glucose monitoring goals.

2.1 Primary Objective (or Aim)

Aim 1: To determine if daily loss aversion financial incentives and use of a tiered sponsor network improves glycemic control as measured by the HbA1c among adolescents and young adults with DM1
## 2.2 Secondary Objectives (or Aims)

**Aim 2**: To determine if daily financial incentives and use of a tiered sponsor network improves adherence to daily glucose monitoring goals (both frequency of monitoring and proportion of values within target range) among adolescents and young adults with DM1.

**Aim 3**: To determine whether daily financial incentives and use of a tiered sponsor network is feasible in adolescents and young adults with DM1, including youth and sponsor feedback on the *Way to Health* platform and interventions.

### 3 INVESTIGATIONAL PLAN

#### 3.1 General Schema of Study Design

Two-arm randomized controlled trial.

#### 3.1.1 Intervention

Participants will be given daily glucose monitoring goals of ≥4 glucose checks per day with ≥1 readings within goal range (70-180 mg/dL) and an iHealth wireless glucometers, which will wirelessly transmit and store their readings to the *Way to Health* portal each day. *Way to Health* is an NIH-funded web-based infrastructure based at the University of Pennsylvania that is used to run behavioral economic intervention studies.

Participants will be randomized to control (usual care) versus intervention using block randomization (block size = 6) and stratified on HbA1c of 8-10% versus >10%.

**Arm 1**: Usual care. Participants randomized to usual care will be sent an electronic one-page handout on glycemic control recommendations, including the daily glucose monitoring goals.

**Arm 2**: Usual care + Intervention. In addition to the electronic one-page handout that will be sent to Arm 1 participants, the intervention includes the following components:

1) **Loss aversion daily financial incentives**: Each participant will start with $60 in a virtual account at the beginning of each month during the intervention period. They will be notified at 10 a.m. each morning by text or email whether or not they met their daily glucose monitoring goals on the day prior. If adherent the day prior, their winnings balance will remain the same. If non-adherent, $2 will be subtracted from their account and the participant will be notified of how much money is left in their potential winnings. Participants will receive their remaining winnings balance at the end of each 30-day period.

2) **Tiered sponsor network**: Each participant will select 2 adult sponsors (e.g., caregiver, friend) who will be automatically notified if the participant is non-adherent to daily glucose monitoring goals. The first tier sponsor will be notified after 2 consecutive days of non-adherence, and the second sponsor notification will occur after 5 consecutive days of non-adherence. Sponsor notifications occur automatically via the *Way to Health* platform either via text or email (per each sponsor’s preference).

#### 3.2 Study Duration, Enrollment and Number of Sites

**3.2.1 Duration of Study Participation**

We will conduct a 6-month randomized controlled trial using *Way to Health* with a 3-month intervention period and 3-month follow-up period.
The study duration for each participant will be 6 months. HbA1c levels at enrollment, 3 months and 6 months will be collected as standard of care (either at diabetes appointments or lab-only visits), and the values collected via chart review.

Participants will be mailed iHealth wireless glucometers and test strips. A research team member will contact the participant by phone to discuss device set-up and will be available for troubleshooting. Calls are likely to last between 5-15 minutes.

A random group of participants in the intervention arm will be selected to participate in exit interviews and focus groups that will last approximately 30 minutes.

3.3 Total Number of Study Sites/Total Number of Subjects Projected

This study is being conducted at The Children’s Hospital of Philadelphia and the University of Pennsylvania. It is expected that up to 90 youth will participate in this study, all recruited from the CHOP Diabetes Center for Children.

3.4 Study Population

3.4.1 Inclusion Criteria

- 14-20 years old
- Diagnosed with DM1
- In suboptimal glycemic control (HbA1c >8.0 within 30 days of enrollment)
- Receive care from The CHOP Diabetes Center for Children (DCC)
- English-speaking
- Own a smartphone (may use iOS, Android, or Windows operating systems)

3.4.2 Exclusion Criteria

- Does not meet inclusion criteria
- Patients newly diagnosed with DM1 (within the past year)
- Patients unable to consent (e.g., severe developmental delay)
- Patients participating in another intervention study that affect how they manage their DM1
- Unstable medical conditions that would likely prevent the subject from completing the study

Participants that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria will be reported in accordance with IRB Policies and Procedures.

4 STUDY PROCEDURES

4.1 Intervention

Participants will be given daily glucose monitoring goals of ≥4 glucose checks per day with ≥1 readings within goal range (70-180 mg/dL) and an iHealth wireless glucometers, which will wirelessly transmit and store their readings to the Way to Health portal each day. Way to Health is an NIH-funded web-based infrastructure based at the University of Pennsylvania that is used to run behavioral economic intervention studies. Participants will be randomized to control (usual care) versus intervention using block randomization (block size = 6) and stratified on HbA1c of 8-10% versus >10%.

Arm 1: Usual care. Participants randomized to usual care will be sent an electronic one-page handout on glycemic control recommendations, including the daily glucose monitoring goals
Arm 2: Usual care + Intervention. In addition to the electronic one-page handout that will be sent to Arm 1 participants, the intervention includes the following components:

1) **Loss aversion daily financial incentives:** Each participant will start with $60 in a virtual account at the beginning of each month during the intervention period. They will be notified at 10 a.m. each morning by text or email whether or not they met their daily glucose monitoring goals on the day prior. If adherent the day prior, their winnings balance will remain the same. If non-adherent, $2 will be subtracted from their account and the participant will be notified of how much money is left in their potential winnings. Participants will receive their remaining winnings balance at the end of each 30-day period.

2) **Tiered sponsor network:** Each participant will select 2 adult sponsors (e.g., caregiver, friend) who will be automatically notified if the participant is non-adherent to daily glucose monitoring goals. The first tier sponsor will be notified after 2 consecutive days of non-adherence, and the second sponsor notification will occur after 5 consecutive days of non-adherence. Sponsor notifications occur automatically via the Way to Health platform either via text or email (per each sponsor’s preference).

4.2 **Screening**

Interested participants will be directed to the Way to Health portal (My.waytohealth.upenn.edu/beincontrol). There, they will provide electronic informed consent or assent and complete eligibility and baseline questionnaires. If participants do not meet the eligibility criteria based on their responses, they will no longer be allowed to enroll in the study.

4.3 **Subject Completion/Withdrawal**

Participants may withdraw from the study at any time without prejudice to their care. They will be required to send a letter or email to the study team indicating that they would like to withdraw from the study. Participants may also be discontinued from the study at the discretion of the study investigators for adverse events or to protect the participants for reasons of safety or for administrative reasons. It will be documented whether or not each participant completes the study. If the Investigator becomes aware of any serious, related adverse events after the subject completes or withdraws from the study, they will be recorded and the IRB and sponsors will be notified according to Institutional policies.

5 **STUDY EVALUATIONS AND MEASUREMENTS**

5.1 **Screening and Monitoring Evaluations and Measurements**

5.1.1 **Demographics**

The following demographic characteristics will be collected:

- Address
- Date of birth
- Social security number
- Gender
- School status/education
- Race/Ethnicity
- Income (if applicable)

5.1.2 **Study Measurements**

HbA1c levels at enrollment, 3 months and 6 months will be collected as standard of care (either at diabetes appointments or lab-only visits). HbA1c values, date of lab test and presence (or not) of accompanying clinic visit will be collected via chart review.
5.1.3 Other Evaluations, Measures

Baseline Survey: All participants will complete a baseline survey asking about: basic demographics; DM1 history (duration, complications, medication regimen); and self-efficacy and social support for diabetes management. We will use validated survey instruments developed by the PI or other researchers in the field. (See attached baseline survey instrument.)

End of Intervention Period Survey: All participants will complete a survey at the end of the intervention period assessing their self-efficacy and social support for diabetes management. We will use validated survey instruments developed by the PI or other researchers in the field. (See attached end of intervention survey instrument.)

Exit Survey: All participants will complete an exit survey that asks about their experience with the intervention and platform as well as follow-up measures of their self-efficacy and social support for diabetes management. We will use validated survey instruments developed by the PI or other researchers in the field. (See attached exit survey instrument.)

Exit Interviews/Focus Groups: Exit interviews and focus groups will be conducted with randomly selected youth (n = 10-15) from the intervention arm for their feedback on the intervention and Way to Health platform from a youth perspective. Interviews will be conducted by research team members who are familiar with the study goals, objectives, and in qualitative interview techniques. We expect the interviews or focus groups to last 20-30 minutes each. Each intervention arm participant will be compensated $20 for their participation in the exit interviews or focus groups.

To ensure confidentiality and anonymity of the interviewees, all study-related recordings and transcripts will be labeled with an identification number only, and the crosswalk between identification numbers to interviewee names will be kept in a password-protected, secured server at the University of Pennsylvania. All voice recordings, transcripts, and analysis of transcripts will be kept confidential and stored on a password protected, secured server at the University of Pennsylvania. Only the investigators will have access to these materials.

All interviews and focus groups will be audio-recorded. Audio-recordings will be uploaded to the secure ADA transcription website (http://www.adatranscription.com), a HIPPA complaint transcription service. Transcripts will be analyzed with NVivo software using grounded theory techniques and thematic analysis.

5.2 Safety Evaluation

Participant safety will be monitored by adverse events. The goals set for participants are within what youth with DM1 would normally be expected to do on a daily basis. The HbA1c checks at 3-month intervals are collected as standard of DM1 care.

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure the personal information to ensure confidentiality. At the time of participation, each participant will be assigned a study identification number via Way to Health. This number will be used on all study materials and in Way to Health. A separate list will be maintained within Way to Health that will link each participant's name to the study identification number for future reference and communication.
6 STATISTICAL CONSIDERATIONS

6.1 Primary Endpoint

The primary endpoint will be glycemic control as measured by HbA1c at 3 months.

6.2 Secondary Endpoints

- Follow-up HbA1c at 6 months
- Number and level of daily glucose checks during the intervention and follow-up periods in the intervention and control groups
- Proportion of participants adherent to daily glucose monitoring goals during the 3-month intervention period compared to the 3-month follow-up period in the intervention and control groups
- Feasibility and feedback on intervention and Way to Health

6.3 Statistical Methods

6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age, percentages for categorical variables such as gender).

6.3.2 Analysis of Primary Outcome of Interest

All participants randomly assigned to a study arm will be included in the intention-to-treat analysis. Primary analyses will use the usual care group as the reference. We will compare baseline characteristics by arm using t-tests and chi-square tests along with regression analyses in which baseline covariates are included as controls. Our main outcome of interest will be change in HbA1c by end of intervention period. We will use a linear mixed model for change in HbA1c at 3 months versus baseline adjusted for HbA1c at baseline using multiple imputation to account for missing data. All hypothesis tests will be 2-sided. We will use Stata and/or SAS to analyze the data. All analyses will be blinded until at least the primary study endpoint has been completed and all statistical analysis plans are in place.

6.4 Sample Size and Power

Power calculations are based on a clinically relevant HbA1c difference of 1.011,20 between the intervention and control groups. Assuming an HbA1c standard deviation of 1.56,11, a power of 0.80, two-sided significance of 0.05, and 20% drop-out rate, we would need a sample of at least 90 participants (45 per arm).

7 SAFETY MANAGEMENT

7.1 Clinical Adverse Events

Clinical adverse events (AEs) will be monitored throughout the study by the study team and reviewed by the Lead Investigator. Youth with DM1 often experience several episodes of mild hypoglycemia per week as part of their usual care. Though no increase in frequency of severe episodes of hypoglycemia is expected since we are promoting increased frequency of monitoring and therefore, heightened awareness of blood glucose values, the research team will monitor for severe hypoglycemia episodes, defined as glucose <50 mg/dL or requiring assistance from others to treat their hypoglycemia. We will use alerts on the Way to Health platform if any participant has a blood glucose reading <50 mg/dL. These alerts will prompt a call to the participant by a research team member who will use a standard script to assess for patient safety and to review safe diabetes management (see attached hypoglycemia script). All cases of severe hypoglycemia will be reviewed with the
study’s Lead Investigator, who will consider whether continuation in the study is appropriate based on patterns of hypoglycemia and additional information participants provide.

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, significant AEs (SAEs) are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study (including SAEs) these will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

8 STUDY ADMINISTRATION

8.1 Data Collection and Management

8.1.1 Confidentiality, Security, and Anonymization

Way to Health

All personal information that the participant is asked to provide will be collected via Way to Health. Way to Health collects subjects’ names, dates of birth, addresses, email addresses, phone numbers, and their social security number (collected for the purposes of reimbursement). They also request the name and phone number of an alternate contact. To ensure that participant confidentiality is preserved, individual identifiers are stored in a single password-protected system that is accessible only to study research, analysis and IT staff. Participants’ social security numbers will be stored in a locked cabinet to be destroyed at a later date. An investigator or statistician who logs in will be able to access only de-identified data. The Way to Health administrative group and research coordinators responsible for contacting participants for follow-up study visits or responding to questions about the study are able to view participant names and contact information. The Way to Health web development team and Project Director currently have administrative access to personal health information (PHI). All of these personnel will have completed Human Subjects Protection and HIPAA privacy training. The system automatically generates logs of all data queries which can be reviewed by research staff to ensure that no unauthorized persons have gained access to identifiable information. This system is hosted on site at The University of Pennsylvania (UPenn) and is protected by a secure firewall and several layers of operational security. Once a participant has been entered into this system, they are given a unique study identification number (ID). Any datasets and computer files that leave the firewall are stripped of all identifiers and individuals are referred to by their study ID. The study ID is also used on all analytical files. The Penn Medicine Academic Computing Services (PMACS) is the hub for the hardware and database infrastructure that supports the project and the Way to Health web portal is built on this infrastructure. The data collected for Way to Health based studies is stored in MySQL databases on a PMACS-operated blade server environment devoted specifically to Way to Health. The data center is housed in Information Systems and Computing at 3401 Walnut Street. All data are stored in a single relational database, allowing researchers to correct mistakes. Every SQL transaction, including accessing and changing data, is logged for auditing purposes. Data are entered into the database through several different mechanisms. Participants enter their own personal information and respond to surveys through a PHP-based web interface. Researchers have a separate interface that allows them to manually enter data if needed. Datasets are blinded of all personally identifiable information when exported for analysis. The web application automatically removes all identifiers when a researcher requests an analytic dataset. The only people with access to identifiable participant information are pre-specified Research Coordinators responsible for contacting participants for follow-up. Personal information and research data will be stored in separate SQL tables and will be linked by a computer-generated ID number. Additionally, any information that leaves this system to communicate with third party data sources (i.e. survey software) is stripped of any identifiers and transmitted in encrypted format. The same unique study ID is used to link these outside data to the participants. All data for this project will be stored on the secure/firewalled servers of the PMACS Data Center, in data files that will be protected by multiple password layers. These data servers are maintained in a guarded facility behind several locked doors, with very limited physical access rights. They are also cyber-protected by extensive firewalls and multiple layers of
communication encryption. Electronic access rights are carefully controlled by UPenn system managers. Way to Health uses highly secure methods of data encryption for all transactions involving each participant's financial information using a level of security comparable to what is used in commercial financial transactions. This multi-layer system of data security, identical to the system protecting the University of Pennsylvania Health System’s medical records, greatly minimizes the risk of loss of privacy. All communications between users and our site will be encrypted with SSL/HTTPs technology.

Of note, the Way to Health has been used in a previous study at CHOP (eIRB 14-011072).

**Qualtrics**

This study is using the online survey tool Qualtrics to collect answers to survey questions from participants. Survey answers are stored on the Qualtrics server before being retrieved and saved on the platform. All interactions between a participant and the Qualtrics server are de-identified. Study staff members review the survey content to ensure that no questions in any of the surveys ask for patient identifiers. To ensure no patient identifiable data is stored by Qualtrics, randomly generated 64 bit identifiers are used to link responses in Qualtrics to study events in the system. No PHI will ever be stored by this application in Qualtrics.

**iHealth**

The iHealth glucometer is designed for consumer use. When a participant receives the device, they download the application on a smartphone, which is where their glucose data will be collected. Participants will then create their own account on the iHealth’s website (http://www.ihealthlabs.eu/en/). The participant must give some identifying information to the iHealth website to create an account (e.g. full name, email address). The iHealth website has its own detailed privacy policy available at http://www.ihealthlabs.eu/en/content/109-your-health-data-in-a-secure-place.

Once a participant has an iHealth account, they authorize the Way to Health platform to access their glucose data via an authentication protocol called OAuth (http://en.wikipedia.org/wiki/OAuth). The platform collects their data over a secure connection, and makes these data available to the Way to Health project via a secure connection.

**8.2 Confidentiality**

All data and records generated during this study will be kept confidential in accordance with Institutional policies on subject privacy and the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. The safeguards described above in Section 8.1 will be implemented to ensure subject confidentiality.

No identifiable data will be used for future studies without first obtaining IRB approval. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes).

**8.3 Regulatory and Ethical Considerations**

**8.3.1 Data and Safety Monitoring Plan**

While there is no data monitoring safety board in place for this study as it is a study with minimal risk, the research team at UPenn and The Children’s Hospital of Philadelphia, led by the Investigators, will be aware of and will monitor possible areas of risk to the research participants. Weekly team meetings will include discussion of any safety and data issues that are observed, including systematic tracking for severe hypoglycemic events. The Lead Investigator will be responsible for notifying the IRB should any risks befall the participants during the execution of this study.
8.3.2 Risk Assessment

The risks of this study are minimal. The burden of study participation is no more than what patients with DM1 would normally be expected to do to manage their disease: check their blood glucose at least 4 times daily with a goal range of 70-180mg/dL and have HbA1c measured at 3 month intervals. The iHealth wireless glucometer devices are also in line with usual care as the only substantial difference between these devices and commonly used glucometer devices is that glucose readings are wirelessly uploaded as opposed to manually downloaded in the clinic. Finally, the intervention is designed to try to reinforce behaviors that are required of routine care.

Participants may lose time completing surveys and getting their HbA1c checked. Participants may experience some discomfort with having their blood drawn for the HbA1c, though this is expected as part of routine DM1 care since standard of care includes a HbA1c measurement every 3 months. Participants will be compensated $20 for the initial HbA1c and survey completion and $30 for each subsequent one.

Participants may feel distressed at losing money if they are not able to adhere to the glucose monitoring goals. Participants will be aware that they can leave the study at any time.

Youth with DM1 often experience several episodes of mild hypoglycemia per week as part of their usual care. Though no increase in frequency of severe episodes of hypoglycemia is expected since we are promoting increased frequency of monitoring and therefore, heightened awareness of blood glucose values, the research team will monitor for severe hypoglycemia episodes, defined as glucose <50 mg/dL or requiring assistance from others to treat their hypoglycemia. We will use alerts on the Way to Health platform if any participant has a blood glucose reading <50 mg/dL. These alerts will prompt a call to the participant by a research team member who will use a standard script to assess for patient safety and to review safe diabetes management (see attached hypoglycemia script). All cases of severe hypoglycemia will be reviewed with the study’s Lead Investigator, who will consider whether continuation in the study is appropriate based on patterns of hypoglycemia and additional information participants provide.

Loss of confidentiality is a potential risk of participating in this study; however, the safeguards put in place by Way to Health (Section 8.1) will reduce this likelihood. Due to the financial incentives in this study, we will be collecting social security numbers so that we can complete W-9 forms for participants. Social security numbers only will be used to generate W-9 forms and will be deleted once they are no longer needed. The members of the study teams will follow necessary precautions to ensure that all collected data are not shared with unauthorized individuals or groups.

8.3.3 Potential Benefits of Study Participation

We do not guarantee any direct benefits will result from participation. However, since we are directly encouraging youth with poor DM1 control to improve their daily blood glucose monitoring, if they are successful, then they will have the potential to avert clinically significant complications of DM1. Additionally, knowledge gained from this study may inform how other youth can improve their DM1 control.

8.3.4 Risk-Benefit Assessment

Anticipated risks of this study should be minimal and the risk/benefit ratio is extremely favorable. Participants are youth with suboptimal control of DM1 who are at high risk for poor health outcomes when non-adherent to their medical regimen both acutely (e.g., diabetic ketoacidosis) and long-term (e.g., macrovascular complications). Our intervention seeks to reinforce behaviors that are required of routine care and could lead to improved health for the participants.

8.4 Recruitment Strategy

Participants will be recruited through The CHOP Diabetes Center for Children (DCC). The first recruitment strategy will be via email. The CHOP DCC has a registry list of >1,000 patients with DM1 who participated in a previous study of patients with DM1 (IRB# 10-007741) who provided their email addresses and expressed interest in being contact for other potential studies. This listserv of patients will be sent a recruitment email
Other recruitment strategies that may be employed if insufficient participants are enrolled from email recruitment will include posted flyers (see attached recruitment flyer) in The CHOP DCC and by word-of-mouth/colleague referrals at CHOP. General recruitment flyers can be found in Section 12 of the application. The flyers will be posted in a variety of locations around CHOP and the DCC. The flyers will direct interested individuals to the Way to Health portal.

All individuals recruited will be asked to enter data related to eligibility and their demographic characteristics through the Way to Health portal (My.waytohealth.upenn.edu/beincontrol).

We may also employ The CHOP recruitment enhancement core to provide additional assistance with recruitment plan development and to identify and contact potential participants on our behalf using the CDW, CHOP Recruitment Registry, and a Centerwatch study listing.

8.5 INFORMED CONSENT/ASSENT AND HIPAA AUTHORIZATION

8.5.1 Consent/Assent of Adolescents and Young Adults

Interested participants will be directed to the Way to Health web portal. The Way to Health portal will take them through an automated online informed assent session for youth <18 years or online informed consent for youth ≥18 years (see attached consent form). Youth <18 years will also be required to have their parents electronically sign for their parental permission or consent. The consent/assent electronic session will be divided into sections and potential participants will have to click a button to advance through each section. This is to help ensure that participants read the consent/assent form thoroughly by breaking down the form into manageable blocks of text. Each section will have a button allowing the user to contact a researcher via email if she has questions about the consent/assent form. Successive screens will cover each section of the consent form (e.g., “Why are you being asked to take part in this study?” “What is the purpose of this research study?”). On the final consent/assent screen, potential participants who click a clearly delineated button stating that they agree to participate in the study will be considered to have assented/consented to enroll.

Investigators will require a phone number and email address be provided for the parent or legal guardian whose electronic signature is provided in the written online consent. A member of the research team will do the following to ensure the identity of the person providing consent/assent: 1) verify that the name listed matches the name listed in the EHR, 2) contact the listed parent or legal guardian by phone (will ask parent or legal guardian to identify child by name and date of birth, then assure that they gave permission for study), and 3) email a pdf of the consent form to the parent or legal guardian.

Participants will be provided with details regarding how to contact the research team via email or phone at any time if they subsequently wish to withdraw from the study. This contact information will remain easily accessible via the participants individual Way to Health portal dashboards throughout the study.

If a participant turns 18 years of age during the 6-month research study period, the participant will be re-consented electronically via the Way to Health portal as described above.

8.6 Payment to Subjects/Families

8.6.1 Reimbursement for travel, parking and meals

No reimbursement for travel, parking or meals will be provided for when participants have their HbA1c drawn since these labs are part of their standard on-going, routine DM1 care. Participants will be provided with iHealth wireless glucometers and the accompanying test strips at no charge. Participants may incur data charges on their smartphone both from text messaging and the use of the iHealth application
8.6.2 Payments

All participants will be paid $20 for completing enrollment, which includes having a baseline HbA1c (either drawn at study enrollment or within 1 month prior to enrollment), completing the baseline survey on Way to Health as well as setting-up the iHealth wireless glucometer and transmitting their first blood glucose reading. Participants in both arms will be paid $30 for having an HbA1c checked and completing a survey at 3 months. Finally, participants in both arms will be paid $30 at study completion if they have an HbA1c checked at 6 months and complete the exit survey on Way to Health. The randomly selected group of youth participants from the intervention group who complete exit interviews or focus groups will be paid $20 for their time. These participant payments will be provided as gift cards.

Participants in the intervention arm will be eligible to win as much as $60 per monthly period if adherent to the daily glucose monitoring goals. This renumeration will be provided via a reloadable bank card.

9 PUBLICATION

We plan to publish the findings in conference proceedings and/or peer-reviewed journals. Only de-identified aggregated data will be published.

10 REFERENCES


